

REMARKS

By the foregoing amendment claims 3-9, and 11, remain pending in the application and are subject to rejections. Reconsideration of these rejections are respectfully requested in view of the following comments.

In the Office Action of January 4, 2008, which is repeated in the Office Action of August 6, 2008, the claims are rejected under 35 U.S.C. 112 second paragraph, allegedly as being indefinite by containing the term “substantially”.

Although the Examiner identified this term in independent claim 1, as well as in claim 12, such a term does not appear in independent claim 3. Accordingly, it is believed that the rejection is therefore moot as to claim 3, (and any other dependent claims thereon). Accordingly, withdrawal of the rejection is respectfully requested.

In the Office Action of January 4, 2008, which rejection is maintained in the Office Action of August 6, 2008, claims are rejected under 35 U.S.C. 103 (a) as obvious over McCauley (U.S. Patent 5,652,365). Although McCauley does disclose a process of preparing a polymorphic form I of Finasteride (citing column 6, lines 4-64, as well as example 3 in claims 1-2), the process disclosed by McCauley does not meet all the limitations in the instant claims.

In the claimed process (represented by independent claim 3) Finasteride Form I is dissolved in a solvent to form a solution in step (i) and the claimed process further requires “distilling off the solvent from the solution obtain in step (i)”.

When considering a pharmaceutical product, such as Finasteride Form I, one of the properties of such a pharmaceutical of high importance is “purity”, wherein purity includes factors such as HPLC purity, ash content and residual solvent content.

Finasteride produced according to example 3 of McCauley yields a product having a high chromatographic purity, but also a high residual solvent content, which is disadvantageous, and makes the product unsuitable for pharmaceutical use. In McCauley,

Response to Office Action dated August 6, 2008
U.S. Appl. No. 10/563,138
Atty. Docket No.: 8693.015.US0000

especially example 3, McCauley precipitates Finasteride from the solvent by addition of a non-solvent, whereas the claimed process of applicant's independent claim 3, distills off the solvent. Thus, the claimed process of distilling off the solvent rather than by combining a solvent with a non-solvent as in McCauley, especially Example 3, is completely different. As disclosed in the present specification, the present invention provides Finasteride form I free of associated impurities (page 4, third full paragraph also see the Examples, beginning with Example 1, beginning on page 5 of the specification). Thus, for the forgoing reasons the McCauley process (especially in Example 3) is inapplicable to independent claim 3, and does not establish a prima facie case of obviousness for the claimed invention. The previous rejections of other independent claims based on McCauley is deemed moot in view of their cancellation and as remaining independent claim 3, does not contain the allegedly objectionable term "substantially", applicants submit that the present claims are now in condition for immediate allowance which action is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1437, under Order No. 8693.015.US0000.

Respectfully submitted,



Date: February 5, 2009

Thomas P. Pavelko
Registration No. 31,689
NOVAK DRUCE & QUIGG LLP
1300 Eye Street, NW
1000 West Tower
Washington, DC 20005
Telephone: (202) 659-0100